

## ENZYMATIC THERAPY

What Better feels like."

INTEGRATIVE THERAPEUTICS INC."

NF Formulas PhytoPharmica

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Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.0467 ENZYMATIC THERAPY'
&
PHYTOPHARMICA'

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

APR 2 0 2004

April 12, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Iberogast®	Iberogast combines Iberis amara with eight other herbs that help maintain healthy muscle tone throughout the intestinal tract and digestive system.*	Proprietary blend of the following herbal extracts: German chamomile (Matricaria recutita) flower, Clown's mustard (Iberis amara) plant, Angelica (Angelica archangelica) root and rhizome, Caraway (Carum carv!) fruit, Milk thistle (Silybum marianum) fruit, Lemon balm (Melissa officinalis) leaf, Celandine (Chelidonium majus) aerial part, Licorice (Glycyrrhiza glabra) root, Peppermint (Mentha x piperita) leaf

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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Iberogast 4e

## fillest

By:	
•	Robert C. Doster
Title:	Senior Vice President of Scientific Affairs
Date:	4/12/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux Chief Financial Officer